DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species 5, mixtures of derivatives polymers of vinyl acetate and crotonic acid (claims 21 and 22) in the reply filed on 4/1/10 is acknowledged.

Claims 1-13 have been cancelled. Claims 18-20, 24, and 26 have been withdrawn from consideration. Claims 14-17, 21-23, 25 and 27-29 are presented for examination as they read on the elected subject matter.

Comment: Please insert the continuity information at the top of page 1 of the specification.

Comment: In claim 25, "allover" should be --- all over ---. Please correct.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings were received on 4/14/06. These drawings are not acceptable because the Figure captions belong in the specification and not in the Figures.

Specification

The specification is missing a section concerning the Figures.

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it

should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Information Disclosure Statement

Applicant has not filed an information disclosure statement. Applicant is reminded of their duty to disclose information material to patentability (see 37 CFR § 1.56). § 1.56 Duty to disclose information material to patentability. (a) (in part) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 22 introduces new matter as the claim recites the limitation:

22. (Currently Amended) Composite biomaterials for bone implants, according to ~~claim No. 18~~ claim No. 15 characterized for having in their composition a proportion of the organic phase between 0.1 and 99%, which is constituted by poly-vinyl acetate-co-vinyl alcohol composition between 1 and 25% molar of monomeric units of vinyl alcohol of molecular mass and purity similar to the one described for the polyvinyl acetate, and further characterized for a composition which is constituted by mixtures of derivative polymers of the vinyl acetate and crotonic acid.

The concept of combining the compositions characterized by different copolymers is a new concept not previously presented. There is no support in the specification for this limitation. There is no guidance in the specification to select this combination of copolymers and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 14-17, 21-23, 25 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14, 21 and 22 recite: "derivates of the vinyl acetate and the crotonic acid."; and "derivative polymers of the vinyl acetate and the

crotonic acid." A derivate is a derivative. The Merriam Webster OnLIne dictionary states that derivative means "a chemical substance related structurally to another substance and theoretically derivable from it". It is therefore unclear which chemical substances are intended by Applicant and thus the meets and bounds of the claims are unclear. The Examiner suggests removing the term 'derivatives'. Claims 15-17, 21-23, 25 and 27-29 are rejected as being indefinite because they are dependent on an indefinite base claim.

2. Claim 14 recites the limitation "the vinyl acetate and the crotonic acid" in line 4. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 25 recites the limitation "the inorganic support" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is unknown what this might be.

4. Claim 27 recites the limitation "the inorganic support" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. It is unknown what this might be.

5. Claims 15-18, 21-23, 25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites: "indistinctly". The plain and ordinary meaning of indistinct means not clearly recognizable or understandable. It is thus unclear how the composite biomatieral can be dense or porous and yet indistinct, not clearly recognizable, as the claim language clearly states that it is dense or porous. Claims 17, 18, 21-23, 25 and 27 are rejected as being indefinite because they are dependent on an indefinite base claim.

6. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is characterized for having in their composition having poly-vinyl

acetate-co-vinyl alcohol and claim 22 is characterized for a composition which is constituted by mixtures of derivative polymers of the vinyl acetate and crotonic acid. It is unclear which composition characterizes the composition. The claims will be examined as they read on the elected subject matter.

7. Claim 27 recites the limitation "successive layers ceramic-polymer-ceramic or polymer-ceramic-polymer". There is insufficient antecedent basis for this limitation in the claim. It is unknown what ceramic this might be. The claims will be examined as they read on the elected subject matter.

8. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 is directed to a bone implant composite biomaterial but the claim also recites implantation into soft tissue. It is unclear how a bone implant can be a soft tissue implant because bone is not soft tissue. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-17, 21-23, 25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furlong et al. (US 5258034) Seppala et al. (US 6290982).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant claims a composite biomaterial for bone implants.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Furlong et al. teach femoral prosthesis (bone implant) that can be made with copolymers of vinyl acetates with crotonic acid (Abstract; column 2, lines 39-44 and claims 1, 2, 5-10). Furlong et al. teach coating the prosthesis with calcium hydroxyapatite (column 3, lines 24-25). The ratio of P/Ca is intrinsically within the instantly claimed range. The origin of the hydroxyapatite is irrelevant as hydroxyapatite will function as hydroxyapatite whether from

natural or synthetic origins. In the absence of evidence to the contrary, the copolymer prosthesis is homogenous and evenly distributed in the whole volume or over any support. Concerning the 'inorganic supports' which lack antecedent basis, it is clear from the disclosure of Furlong et al. that not only is the implant in contact with bone, a calcium/phosphorus inorganic substrate, but also bone grows into the implant (see Abstract; column 1, lines 24-62 and figure 1). Thus, live tissue can be formed at the surface contact with the copolymer.

Seppala et al. teach adding pharmaceutical agents to implants (claims 2 and 13).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Furlong et al. is that Furlong et al. do not expressly teach a single embodiment of a biomaterial with calcium salts and copolymers of vinyl acetate and crotonic acid where it is dense and porous and the pores of the biomaterial are three dimensionally interconnected with diameters from 5 to 840 microns or their physical form in either blocks or granules.

2. The difference between the instant application and Furlong et al. is that Furlong et al. do not expressly teach a proportion of 0.1 and 99% of the organic phase.

3. The difference between the instant application and Furlong et al. is that Furlong et al. do not expressly different speeds of reabsorption between 10^{-5} and 3.2% per day.

4. The difference between the instant application and Furlong et al. is that Furlong et al. do not expressly teach adding drugs to the implant. This deficiency in Furlong is cured by the teachings of Seppala et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to a biomaterial of Furlong et al. with calcium salts and copolymers of vinyl acetate and crotonic acid where it is dense or porous and the pores of the biomaterial are three dimensionally interconnected with diameters from 5 to 840 microns or their physical form in either blocks or granules and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because since the same copolymer is used as instantly claimed then the porosity will be intrinsically same in the absence of evidence to the contrary. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Regarding the physical form of either blocks or granules, this is simply a matter of shaping the prosthetic by one of ordinary skill in the art into blocks or granules if they desired that physical form. The biomaterial composition does not change its constituents.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to a biomaterial of Furlong et al. with a proportion of 0.1 and 99% of the organic phase and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine

practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to a biomaterial of Furlong et al. with different speeds of reabsorption between 10-5 and 3.2% per day and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is intrinsic to the composition of Furlong et al. in the absence of evidence to the contrary. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add drugs to the implant of Furlong et al., as suggested by Seppala et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Seppala et al. establish the concept of adding pharmaceutical agents to implants/prosthetics (Abstract and claims 1, 2 and 13) and it would be obvious to add pharmaceutical agents to the prosthetic of Furlong et al. to enhance the healing process.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, for implantation into soft tissue, however, the intended use of the

claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Primary Examiner, Art Unit 1616